

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LYNN OXENBERG and RONALD LEWIS

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity
as Secretary of the United States Department
of Health and Human Services,

Defendant.

Civil Action No. 20-738-CMR

ANSWER TO COMPLAINT BY DEFENDANT ALEX M. AZAR II

Pursuant to Federal Rule of Civil Procedure 12, Defendant Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services (“HHS”), answers Plaintiffs’ Complaint as follows:

PRELIMINARY STATEMENT

1. Denied as a conclusion of law to which no response is required.
2. Denied as a conclusion of law to which no response is required.
3. Denied as a conclusion of law to which no response is required.
4. To the extent this introductory paragraph makes factual averments regarding Plaintiffs’ medical condition or treatment and the underlying administrative claims, Defendant refers to his more specific responses below. To the extent that a response is deemed required, denied as a conclusion of law to which no response is required.

JURISDICTION

5. Denied as a conclusion of law to which no response is required. Defendant does not intend to contest jurisdiction.

6. Denied as a conclusion of law to which no response is required. Defendant does not intend to contest venue.

PARTIES

7. Admitted to the extent that Plaintiff Ronald Lewis is an individual and is eligible for Medicare. Defendant lacks knowledge or information sufficient to form a belief about Plaintiff Lewis' state of residency or principal address at the time of Complaint filing; however, Defendant admits that the address identified in the Complaint matches the address at which Plaintiff Lewis received correspondence regarding the administrative decision on appeal. Defendant reserves his right to argue that Plaintiffs' appeals have been improperly joined.

8. Admitted to the extent that Plaintiff Lynn Oxenberg is an individual and is eligible for Medicare. Defendant lacks knowledge or information sufficient to form a belief about Plaintiff Oxenberg's state of residency or principal address at the time of Complaint filing; however, Defendant admits that the address identified in the Complaint matches the address at which Plaintiff Oxenberg received correspondence regarding the administrative decision on appeal. Defendant reserves his right to argue that Plaintiffs' appeals have been improperly joined.

9. Admitted.

LEGAL BACKGROUND

10. Denied as a conclusion of law to which no response is required.

11. Denied as a conclusion of law to which no response is required.

12. Denied as a conclusion of law to which no response is required.

13. Denied as a conclusion of law to which no response is required.

FACTUAL BACKGROUND

A. Tumor Treatment Field Therapy (TTFT)

14. Admitted to the extent that glioblastoma multiforme (“GBM”) is a type of brain cancer. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph. To the extent that a response is deemed required, these allegations are denied.

15. Admitted to the extent that tumor treatment field therapy (“TTFT”) uses alternating electrical fields and has been developed as a treatment for GBM. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph. To the extent that a response is deemed required, these allegations are denied.

16. Admitted to the extent that papers concerning TTFT were published in the Journal of the American Medical Association in 2015 and 2017 and the contents of those papers speak for themselves. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph. To the extent that a response is deemed required, these allegations are denied.

17. Admitted to the extent that the National Comprehensive Cancer Network assigns TTFT a Category 1 recommendation as a treatment option for newly diagnosed GBM, following initial maximal debulking surgery (when feasible), chemotherapy, and radiation therapy. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph. To the extent that a response is deemed required, these allegations are denied.

18. Admitted to the extent that Novocure, Inc. is a supplier of the equipment that delivers TTFT and that their product is called the Optune system. Also admitted to the extent that the Optune system is rented on a monthly basis and that Medicare beneficiaries may submit monthly claims for Medicare payment. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph. To the extent that a response is deemed required, these allegations are denied.

B. The Medicare Appeals Process

19. Admitted to the extent that this paragraph generally describes the Medicare claim appeal process, which is governed by the applicable Medicare laws and regulations, as described in Defendant's Memorandum of Points and Authorities in Support of his Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment.

20. Admitted to the extent that Administrative Law Judges and the Medicare Appeals Council are generally required to issue decisions within 90 days, although these deadlines may be waived or extended as provided by the Medicare statute and regulations. *See* 42 U.S.C. § 1395ff(d); 42 C.F.R. §§ 405.1016, 405.1100. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph. To the extent that a response is deemed required, these allegations are denied.

C. Facts Specific to Mr. Lewis

21. Admitted.

22. Admitted that, on October 24, 2019, ALJ Hynum issued a decision in ALJ Appeal No. 3-8693279102 authorizing coverage of Plaintiff Lewis' TTFT claims from November 2018 – May 2019. Also admitted that the Secretary did not appeal that decision, which has become final.

Defendant reserves the right to argue that this decision is irrelevant because it is not before the court on judicial review.

23. Admitted that, on May 30, 2019, ALJ Levine issued a decision in ALJ Appeal No. 1-8411344383 affirming denial of coverage of Plaintiff Lewis' TTFT claims from July – October 2018. ALJ Levine's decision speaks for itself and Plaintiff's characterization of it is denied as a conclusion of law to which no response is required.

24. Admitted.

25. Admitted.

26. Denied as a conclusion of law to which no response is required. Defendant does not intend to contest jurisdiction.

D. Facts Specific to Ms. Oxenberg

27. Admitted.

28. Admitted that, on June 3, 2019, ALJ Strafuss issued a decision in ALJ Appeal No. 1-8452468241 authorizing coverage of Plaintiff Oxenberg's TTFT claims from July – October 2018. ALJ Strafuss' decision speaks for itself and Plaintiff's characterization of it is denied as a conclusion of law to which no response is required. Admitted that the Secretary did not appeal that decision, which was become final. Defendant lacks knowledge or information sufficient to form a belief about ALJ Appeal No. 1-8380637906, which is not attached to or described further in Plaintiffs' Memorandum of Law in Support of their Motion for Summary Judgment [Dkt. No. 12]. To the extent that a response is deemed required as to ALJ Appeal No. 1-8380637906, these allegations are denied. Defendant reserves the right to argue that these decisions are irrelevant because they are not before the Court on judicial review.

29. Admitted that, on September 5, 2019, ALJ MacDougall issued a decision in ALJ Appeal No. 1-8393258352 affirming denial of coverage of Plaintiff Oxenberg's TTFT claims from April – June 2018. ALJ MacDougall's decision speaks for itself and Plaintiff's characterization of it is denied as a conclusion of law to which no response is required.

30. Admitted.

31. Denied as a conclusion of law to which no response is required. Defendant does not intend to contest jurisdiction.

COUNT I

32. Paragraph 32 only incorporates the prior allegations of the Complaint. Defendant therefore incorporates and repeats its answers to each of the preceding paragraphs of the Complaint.

33. Denied as a conclusion of law to which no response is required.

COUNT II

34. Paragraph 34 only incorporates the prior allegations of the Complaint. Defendant therefore incorporates and repeats its answers to each of the preceding paragraphs of the Complaint.

35. Denied as a conclusion of law to which no response is required.

COUNT III

36. Paragraph 36 only incorporates the prior allegations of the Complaint. Defendant therefore incorporates and repeats its answers to each of the preceding paragraphs of the Complaint.

37. Denied as a conclusion of law to which no response is required.

COUNT IV

38. Paragraph 38 only incorporates the prior allegations of the Complaint. Defendant therefore incorporates and repeats its answers to each of the preceding paragraphs of the Complaint.

39. Denied as a conclusion of law to which no response is required.

COUNT V

40. Paragraph 40 only incorporates the prior allegations of the Complaint. Defendant therefore incorporates and repeats its answers to each of the preceding paragraphs of the Complaint.

41. Denied as a conclusion of law to which no response is required.

COUNT VI

42. Paragraph 42 only incorporates the prior allegations of the Complaint. Defendant therefore incorporates and repeats its answers to each of the preceding paragraphs of the Complaint.

43. Denied as a conclusion of law to which no response is required.

PRAYER FOR RELIEF

The “WHEREFORE” paragraph merely states the relief plaintiff seeks. It is not a factual allegation, and therefore no response is required to it. Defendant further denies that Plaintiffs are entitled to judgment or any of their requested relief.

JURY DEMAND

Pursuant to 42 U.S.C. § 405(g) (made applicable to Medicare by 42 U.S.C. § 1395ii), review of the administrative decisions at issue is by judge only and Plaintiffs are not entitled to a trial by jury.

AFFIRMATIVE DEFENSES

Without assuming the burden of proof on any matters where that burden rests on Plaintiffs, Defendant asserts the following affirmative and other defenses with respect to the claims that:

1. Plaintiffs fail to state a claim upon which relief can be granted.

Defendant has, or may have, additional affirmative defenses that are not known to it at this time. Defendant specifically preserves those and other affirmative defenses.

For the reasons set forth above, the Court should affirm the final agency decisions, Plaintiffs' claims against Defendant should be dismissed and all claims for relief asserted by Plaintiffs should be denied.

Respectfully submitted,

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United States Attorney

/s/ Susan R. Becker

for Gregory B. David
GREGORY B. DAVID
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Dated: April 20, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this day, I caused a true and correct copy of the foregoing answer to be served on all counsel of record via the Court's CM/ECF system.

/s/ Matthew E. K. Howatt

MATTHEW E. K. HOWATT

Assistant United States Attorney

Dated: April 20, 2020